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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,484	11/09/2001	Christian Meier	212248US0PCT	5700

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,484	MEIER ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/14/05 & 5/16/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

DETAILED ACTION

Status of the Application

Receipt of the Amendment (specification & claims) and Applicant's Arguments/Remarks filed 03/14/05 and the Information Disclosure Statements (IDS) filed 03/14/05 and 05/16/05 are acknowledged.

The 35 U.S.C. §102(b) rejection of claims 1, 2, 5, 6 and 8-10 over Tomoaki *et al.* (JP 01-113322) has been withdrawn.

Claims 1-19 are pending. Claims 1-11 have been amended. New claims 13-19 have been added. Claims 1-19 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tomoaki *et al.* (JP 01-113322) in view of Lippmann *et al.* (US Pat. No. 4,259,315).

Tomoaki *et al.* teach an aqueous emulsion consisting of copolymers produced by the emulsion polymerization of (a) an alkyl acrylate (ethyl acrylate), (b) an alkyl methacrylate (methyl methacrylate) and (c) a hydroxyalkyl methacrylate (2-hydroxyethyl methacrylate). A drug containing a specific active component is coated with the emulsion. The ratio of the copolymerized monomers (A/B) is 3:1-1:3 (see Abstract).

To prepare the emulsion, an emulsifier (sodium dodecyl sulphate – SDS) is dissolved in distilled water and a mixture of monomers is added and emulsified (alkylester acrylate: alkylester methacrylate = 3:1-1:3. The total of alkylester acrylate and alkylester methacrylate: hydroxyalkyl methacrylate = 2:1-10:1. As the alkylester or acrylate: ethyl acrylate, methyl acrylate and butyl acrylate are preferred. As alkylester methacrylate: methyl methacrylate, ethyl methacrylate and butyl methacrylate are preferred. As hydroxyalkyl methacrylate: 2-hydroxymethyl methacrylate is preferred). The mixture is stirred in a stream of nitrogen. A reaction-initiating agent as ammonium persulphate (APS) is preferably added and the reaction is continued for a fixed time. During the reaction, APS is added. After the reaction, the mixture solution is filtered to give the desired copolymer emulsion.

Tomoaki *et al.* teach that coating at a lower temperature than the softening point of the coat is possible. The elution time of a coated drug can also be controlled in a digestive organ, independently of pH.

With respect to the instant amounts and ranges, no criticality is observed in the instant amounts/ranges since one of ordinary skill in this art could readily determine suitable or effective

amounts/ranges through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters. Tomoaki *et al.* teach the incorporation of drug and emulsifier in the emulsion.

With regard to claim 13, which recites a '(meth)acrylate monomer containing C_1 to C_4 alkyl radicals', Tomoaki *et al.* teach an alkyl methacrylate, such as methyl methacrylate and thus, meets this claim limitation.

Tomoaki *et al.* do not explicitly teach a drug from the instant selective group and do not teach a non-ionic emulsifier. It is deemed obvious to one of ordinary skill in the art to employ any suitable emulsifier or drug, based on the desired or intended purpose. The generic 'drug containing specific active component' disclosed by Tomoaki *et al.* would encompass the species of drugs instantly recited. As noted above, Tomoaki *et al.* teach an anionic emulsifier (*i.e.*, sodium dodecyl sulphate) and do not teach a nonionic emulsifier.

Lippmann *et al.* ('315) teach pharmaceutical compositions for treating potassium deficiency that comprise pharmaceutically acceptable surfactants, such as nonionic and anionic surfactants. These surfactants are taught to be particularly useful in pharmaceutical systems for their compatibility, stability and non-toxicity (see reference column 5, lines 28-32) and Abstract. According to Lippman *et al.*, a suitable surfactant (or combination thereof) for use in the invention is one that has a hydrophile-lipophile balance number (HLB) in excess of 10. Mixtures of surfactants can also be used (col. 4, line 64 – col. 5, line 27).

Therefore, it would have been deemed obvious to one of ordinary skill in the art at the time the invention was made to incorporate the nonionic surfactants of Lippman *et al.* into the

aqueous emulsion of Tomoaki *et al.* because Lippman *et al.* teach pharmaceutical compositions that comprise nonionic and anionic surfactants, and they teach that these surfactants (nonionic, anionic) are particularly preferred because they provide for compatibility, stability and non-toxicity to pharmaceutical formulations. The expected result would be an effective, biocompatible stable formulation for use in pharmaceutical applications.

Given the combined teachings of Tomoaki *et al.* and Lippmann *et al.*, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 03/14/05 have been fully considered.

Applicant's arguments with regards to the 35 U.S.C. §102(b) rejection have been considered and were found persuasive. Accordingly, the 35 U.S.C. §102(b) rejection of claims 1, 2, 5, 6 and 8-10 has been withdrawn.

Applicant argued regarding the 35 U.S.C. §103(a) rejection of claims 3, 4, 7, 11 and 12 over Tomoaki et al. (JP 01-113322) stating, "Tomoaki et al. fail to disclose or suggest a dispersion having a nonionic emulsifier having an HLB of from 15.2 to 17.3. Tomoaki et al. only disclose an anionic emulsifier such as sodium dodecyl sulphate. The specification discloses that the HLB value of the emulsifier has a distinct influence on the crystallization of the emulsifier. If the HLB is above the claimed range, the emulsifiers crystallize. If HLB is below the claimed range, the emulsifiers are unable to stabilize the emulsion sufficiently. Superior

results obtained with the claimed emulsifier are demonstrated in the examples, particularly at page 14. These superior results of the claimed emulsifier are not disclosed or suggested by Tomoaki et al. The anionic emulsifiers of Tomoaki et al. cannot be simply substituted with the claimed nonionic emulsifiers having an HLB of 15.2 to 17.3."

Applicant's arguments have been fully considered, but were not found persuasive. Admittedly, while Tomoaki et al. teach the inclusion of an anionic emulsifier, as opposed to the nonionic emulsifier instantly claimed, it is the position of the Examiner that Applicants have not demonstrated any unexpected and/or unusual results that accrue from the use of the particular non-ionic emulsifier claimed, nor the lower HLB value of the non-ionic emulsifier recited. Tomoaki *et al.* teach an aqueous emulsion consisting of copolymers produced by the emulsion polymerization of (a) an alkyl acrylate (ethyl acrylate), (b) an alkyl methacrylate (methyl methacrylate) and (c) a hydroxyalkyl methacrylate (2-hydroxyethyl methacrylate), wherein a drug containing a specific active component is coated with the emulsion. Lippmann *et al.* is cited to demonstrate the obviousness of employing either nonionic or anionic surfactants in pharmaceutical formulations. The nonionic and anionic surfactants are compatible, impart stability and are non-toxic in medicinal formulations. Additionally, Lippmann *et al.* teach and recognize that suitable surfactants are those that have an HLB value of greater than 10. The prior art clearly teaches emulsion preparations formulated for the same field of endeavor, to treat similar problems, as that desired by Applicants. Thus, given the teachings of the prior art, the instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh

Patent Examiner

Art Unit 1615

June 01, 2005

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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